EXHIBIT M

WORK INSTRUCTION FOR NEW PRODUCT DESIGN CONTROL

PR800-011 Version 4 APPENDIX I - V

Version	Summary of Change	Form
		Changed?
4	Update procedure to include clarification of user needs, design outputs, design reviews, and design changes. Updated Appendix II to reflect clarifications. Additional references included. (CP2002GXJ001)	Yes

^{*&}quot;Capitalized product names are trademarks of ETHICON" (Refer to the rules of proper trademark usage located on the ETHICON Intranet.)

** Changes
/// Deletions

SCOPE:

- This procedure applies to the development of new products. See PR800-012, Work Instructions for Design Changes to Existing Products, if you are making a change to an existing product.
- This procedure applies to all Business Units governed by Ethicon Quality Systems.
- Components provided by Ethicon to another company for their device are governed by either the other company's Design Control System or this procedure, as agreed upon between the two companies.
- The development of new products designed/developed by an external company wherein their Design Control System is deemed appropriate by an Ethicon approved assessment is governed by the other company's Design Control System. In all other cases the development is governed by this document.

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- This procedure does not apply to Class I devices except for the following:
 - 1) When required by any market (country) in which the device is going to be released.
 - 2) Devices noted in Sec. 820.30 of 21 CFR Part 820.
 - 3) All Class I exempt devices must have documentation of functionality, Biocompatibility, sterility, stability, and risk analysis at a minimum and must be effectively transferred to production.

OVERVIEW

This document describes the Design Control Process, which begins once a Project Leader has been assigned, Project Team has been assembled, and the project enters Feasibility. (The project has been approved into the Pipeline. The idea or initiative is officially recognized as a project and will be given the support and resources needed to fulfill the NPD requirements.)

The Worldwide Vice President of Research and Development is the owner of the Design Control Process.

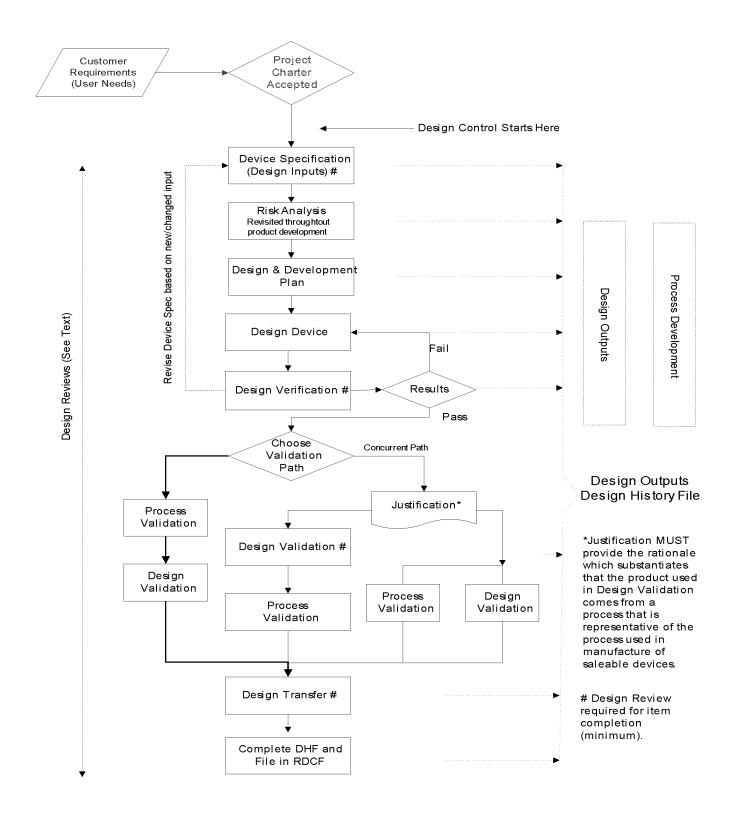
This document describes the following activities:

- Obtaining User Needs (Including Intended Use)
- Creating Product Description
- Creating Device Specification (Design Inputs)
- Performing Risk Analysis
- Creating the Design & Developing Plan (D&D Plan)
- Creating Design Outputs
- Performing Design Verification (Design Outputs Vs Design Inputs)
- Performing Process Development & Validation
- Performing Design Validation
- Performing Design Transfer (Design Outputs are finalized)
- Conducting Design Reviews
- Assembling and Completing a Design History File

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** Flowchart of New Product Design Control Process



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IMPORTANT: All required documentation and all revisions to such must be filed in DHF.

Obtaining User Needs (Including Intended Use)

	Activity	Responsibility
1.	Obtain user needs/intended use via	Marketing in collaboration
	appropriate methodology for Voice of the	with R&D (include other
	Customer.	functions as needed)
2.	Sources of information may include but are	Marketing & Project Team
	not limited to customer feedback, customer	
	complaints, market research, customer	
	visits, surveys, focus, groups, etc.	
3.	Document and file user needs/intended use	Marketing
	and source of information (including Who,	
	What, When, How obtained & by Whom).	
	(File in Marketing in a retrievable fashion)	

Creating the Product Description

	Activity	Responsibility
1.	Complete Product Summary section of Product Description on Appendix 1.	Marketing
	IMPORTANT:	
	• It is not required that all customer requirements or device specifications be determined prior to issuing the initial Version.	
	• For devices with computer systems refer to OP603-276 for CSV deliverables.	
2.	Complete User needs/Intended use and Source on Appendix II.	Marketing
3.	Identify and document the methodology to resolve all ambiguous and conflicting user needs/intended use.	Project Team
4.	Resolve all issues.	Project Team

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Creating the Product Description

	Activity	Responsibility
5.	Document resolution and attach to Appendix II.	Marketing
6.	Obtain approval on Product Description from Product Director & Business Unit R&D Vice President.	Project Leader
7.	Forward all documentation to Project Leader.	Marketing
8.	File all documentation in DHF.	Project Leader
9.	Update and Review the Product Description when appropriate to document changes.	Project Leader

IMPORTANT: Anytime there is a change to the user needs/intended use, the impact to the Product Description Document and Device Specification must be addressed. Also, with any change to the Device Specification, the impact to the user needs/intended use must be addressed.

Creating Device Specification (Design Input)

	Activity	Responsibility
1.	Translate Product Description into	R&D in collaboration with
	measurable technical characteristics.	Marketing (include other
		functions as needed)
AT	TENTION: This includes labeling &	
	packaging.	
2.	Complete Device Specification	Project Team
	documentation on Appendix II.	
3.	Perform Design Review.	Project Team
4.	Gain approval on Device Specification from	Project Leader
	Business Unit R&D Vice President and	
	Group Product Director.	
5.	File all documentation in DHF.	Project Leader

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Creating Device Specification (Design Input)

Activity	Responsibility
6. Update and Review Device Specification	Project Leader
when appropriate to document changes to	
the Device specification. (Any changes to	
the Device specification must be approved	
as stated above.)	
IMPORTANT: Ensure that user	
needs/intended use is not impacted.	

IMPORTANT: Anytime there is a change to the user needs/intended use the impact to the Product Description Document and Device Specification must be addressed. Also, any change to the Device Specification the impact to the intended need of the user must be addressed.

Performing Risk Analysis

	Activity	Responsibility
1.	Assign Risk Analysis Leader to perform Risk Analysis.	Project Leader
2.	Perform and document Risk Analysis per PR602-003 & OP650-010.	QAE
II	MPORTANT: Critical Quality Parameters should be identified via these procedures.	
3.	Evaluate Risk Analysis.	QAE
4.	Determine the next steps.	Project Leader
5.	closure of issues.	QAE
6.	File Risk Analysis and each revision in the Design History File.	Project Leader

IMPORTANT: Risk Analysis should be performed at various stages throughout product development. When design changes are made risk analysis should be performed to ensure that impact of the changes are assessed.

Creating Design & Development Plan

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	Activity	Responsibility
1.	Develop an overall development strategy and communicate it to the team members.	Project Leader
2.	Assign and document the team member who is functionally responsible for preparation of each section of the D&D Plan per Appendix III.	Project Leader
3.	Develop & document strategy(s)/plan(s) for assigned section(s) of the D&D Plan. (Include departments and/or functions interfacing to complete this plan.)	Assigned Team Member
4.	Forward documentation to the Project Leader and appropriate management.	Assigned Team Member
5.	Compile strategy(s)/plans into the D&D Plan per Appendix III (after completion of Version 1 of the Device Specification).	Project Leader
6.	Review D&D Plan with Project Team.	Project Leader
7.	Obtain approval on D&D Plan from R&D Vice President for Business Unit.	Project Leader
8.	File D&D Plan in DHF.	Project Leader
9.	Execute the D&D Plan.	Project Team
10.	Update, Review & Approve the D&D Plan and impact to Risk Analysis when appropriate and document changes as they occur.	Project Leader

Important: D&D plan should include rationale for choosing the validation path (See flow chart on page 3 of this document).

Creating Design Outputs

Activity	Responsibility
1. Create Design Outputs per all approved	Project Team Members
controlled procedures throughout the Design	

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Creating Design Outputs

[Activity	Responsibility
	and Development process. (e.g., raw	
	material specifications, finished goods	
	specifications, technical drawings, labeling	
	and packaging specifications including	
	IFUs)	
	IMPORTANT : Any changes to these must	
	be controlled through the change mechanism	
	for the procedure and/or output required.	
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	2. Ensure all appropriate essential Design	Project Leader
-	Outputs are identified	
	3. Ensure Design Output documents are	Project Leader
Į	approved prior to Design Transfer	

** Documenting Design Changes During Development

Activity	Responsibility
1. During development of the device, changes	Project Team
may occur in order for the device to conform	
to documented Design Inputs (Device	
Specifications). Such changes shall be	
documented and filed in the DHF.	
ATTENTION: When changes are made to	
Appendix II (i.e., Device Specification,	
User Needs, etc.), all subsequent Design	
Control activities (reference the	
"Flowchart of New Product Design	
Control Process") shall be revisited to	
determine impact and potential need to	
repeat or revise affected items.	
2. File design change documentation in the	Project Leader
DHF.	

ATTENTION: Changes to the Appendix II require approvals. Refer to PR573-014, Work Instructions Governing Ethicon Change Control Procedures, for procedures needing to be considered when making changes.

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Performing Design Verification

	Activity	Responsibility
AT	Write the appropriate number of protocols to ensure each requirement in the Device Specification has been met by the design ⁺⁺ . TENTION : This includes labeling and packaging requirements.	R&D Team Member (s)
2.	Obtain approvals for the protocols by QAE at minimum. (other functional groups as appropriate)	R&D Team Member (s)
3. E	Insure that appropriate test methods have been validated per PR800-002.	QAE Team member
4.	Conduct the testing per the protocols.	R&D or appropriate functional department
	Document the results of each test and forward all documentation to the Project Leader.	R&D Team Member (s)
	Investigate root cause and determine appropriate solution if this verification does not indicate that the design meets all requirements in the Device Specification. Document and file in DHF. Repeat Design Control steps as necessary.	Project Team
	Update Appendix II in the Design Verification Column with the location and identifier for the Results for each requirement.	Project Leader
8.	Perform Design Review.	Project Team
9.	File appropriate documentation in the DHF.	Project Leader

** IMPORTANT: Design verifications can occur throughout the design development process. The final design verifications must be conducted as indicated above.

Performing Process Development & Validation

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	Activity	Responsibility
1	. Perform Process Development &	Project Leader & Team
	Validation(s) per PR161-001, Work	
	Instructions for Equipment and Process	
	Control Procedure.	

Performing Design Validation

Design Validation			
	Activity	Responsibility	
Develop Design Validation Strategy. IMPORTANT: The Design Validation Strategy must include actual/simulated use testing for all intended indicated uses, packaging, labeling, etc.		Project Leader & Team (ensure Marketing and Medical Affairs participation)	
2.		Project Leader	
3.	Generate a protocol which reflects the strategy.	Assigned Team Member	
4.	Review the Design Validation Protocol at a formal Design Review prior to conducting the Design Validation IMPORTANT: • A Medical Affairs person must be in attendance for this part of the Design Review if the Validation includes cadaveric or human clinical trials. • Corporate Product Characterization (CPC) must be in attendance if animal trials will be included.	Project Leader	
5.	Gain approval on the protocol from QAE,	Project Leader	

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Performing Design Validation

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	Regulatory and Marketing team members.	
	IMPORTANT:	
	a) Medical Director must approve if human	
	clinical trials are used.	
	b) CPC must approve if internal animal	
	studies are supporting this validation.	
6.	Schedule the Studies.	Marketing
7.	Conduct the Studies.	Marketing, Medical
′ ·	Conduct the Studies.	Affairs, CPC, and R&D
8.	Document the results.	Appropriate Functional
6.	Document the results.	Department
9.	Write Completion Report and forward	Appropriate Functional
	appropriate documentation to Project	Department
	Leader.	Dopurtment
10.	Perform formal Design Review.	Project Team
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11.		Project Leader
	• Investigate root cause.	
	• Determine appropriate solution if this	
	validation does not indicate that the	
	design meets all the requirements in the	
	Device Specification and user	
	needs/intended use.	
	 Document and file in DHF. 	
	• Repeat Design Control steps as	
	necessary. Ensure that the device	
	specification meets the user	
	needs/intended use.	
12.	Update Appendix II in the Design	Project Leader
	Validation Column with the location and	
	identifier for the results for each	
	requirement.	
13.	File appropriate documentation in the DHF.	Project Leader

IMPORTANT: Design Validation occurs after Design Verification. When conducting Design Validation studies, <u>coaching</u> of users is not included.

Performing Design Transfer		
	Activity	Responsible
1.	Schedule a design review after successful completion of Process and Design Validations.	Project Leader
2.	Conduct the design review.	Design Review Team
3.	Confirm the completion of all the items on the Design Transfer Checklist (Appendix IV).	Design Review Team
	IMPORTANT: Ensure all applicable protocols used in the validation of the product are made obsolete in the DMS System.	
4.	During the design review, fill out and approve Design Transfer Checklist (Appendix IV).	Project Leader and Designated Approvers
5.	File Design Transfer Checklist (Appendix IV) documentation in Design History File.	Project Leader

IMPORTANT: A representative from each manufacturing location must be included to review the applicable manufacturing operations that are performed at that location.

Conducting Design Review(s)

Activity	Responsibility
1. Schedule a Design Review consistent with	Project Leader
the D&D plan.	
IMPORTANT: Additional Design	
Reviews can be conducted as needed.	

Conducting Design Review(s)

<u></u>	Activity	Responsibility
2.	Determine discussion topics, discussion	Project Team
	leaders, and participants.	
	IMPORTANT: At minimum, it must	
	include:	
	- Project Leader,	
	- Appropriate Project Team Members,	
	- Specialist personnel as required,	
	- Designated facilitator,	
	- Designated minute recorder, and	
	- Independent Observer(s) i.e., someone	
	who does not have direct responsibility	
	for design stage being reviewed.	
	Determine the decree station required to 1	Duning t I and a
3.	Determine the documentation required to be reviewed and identify the person(s)	Project Leader
	responsible for providing that	
	documentation.	
	IMPORTANT: This documentation	
	should be distributed prior to the meeting	
	with adequate time for review.)	
	with adequate time for review.)	
4.	Publish the schedule and agenda.	Project Leader
5.	Conduct the Meeting.	Facilitator
6.	Evaluate all Design Outputs including the	Project Team &
	design; identify issues, potential problems,	Independent Observer(s)
	resource issues or gaps, Design Control	. ,
	activities, adherence to the D&D plan and	
	gain agreement on future actions. Ensure	
	that all appropriate essential Design Outputs	
	have been identified.	
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7.	Document the decisions, action items and	Minute Recorder
	person responsible for closing the item.	D ' . I 1
8.	The Project Leader must communicate all	Project Leader
	action items resulting from the Design	
	Review to appropriate Management	
	Personnel.	Indopondent Observer(s) 0
9.	Determine and document in the minutes the	Independent Observer(s) &
	manner in which the Independent Observer	Project Team

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Conducting Design Review(s)

Activity	Responsibility
will review the results from each action	
item.	
10. Complete & publish the meeting minutes.	Minute Recorder
11. File a copy of the meeting minutes in the	Project Leader
DHF.	

Assembling & Completing a Design History File

	Activity	Responsibility
1.	Prepare a binder for the DHF; label for the project and include the Design History File Template.(Appendix V)	Project Leader
2.	Determine the contents of the DHF considering the DHF Template in Appendix V.	Project Team
3.	As each identified item is completed or supporting documentation is received, place the documentation into the DHF.	Project Leader
4.	Compile the contents into an organized fashion along with a table of contents. (Note: originals or copies of documents are acceptable.).	Project Leader
5.	Transfer contents into Acco Binder preparing for archiving in RDCF.	Project Leader
6.	Review and verify contents for appropriateness, completeness, and required approvals.	Project Leader
7.	Ensure all action items from Design Reviews have been closed and documented.	Project Leader
8.	Sign and date the DHF Template (Appendix V) when DHF is complete.	Project Leader

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Assembling & Completing a Design History File

Activity	Responsibility
9. Verify the DHF for completeness.	QA or RA Team Member
10. Sign and date the DHF Template (Appendix V).	QA or RA Team member
11. File DHF in RDCF.	Project Leader
12. Prepare and forward receipt of DHF to Project Leader.	RDCF Coordinator
13. Receive Receipt.	Project Leader

IMPORTANT: After a Device Specification has been initiated and as you develop and test your design any change to your design should be documented and filed in the DHF.

APPENDICES

APPENDIX	TITLE
Appendix I	Product Description Document
Appendix II	Relationship between User Needs/Intended Use,
	Device Specification, Design Verification, Process
	Control, Design Validation
Appendix III	Design & Development Plan
Appendix IV	Design Transfer Review Checklist
Appendix V	Design History File Template

All appendices are controlled forms and are detached from the body of this document.

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REFERENCES

DOCUMENT #	DOCUMENT TITLE
PR120-004	Work Instructions for Ethicon Inc's External
	Manufacturers
PR573-014	Work Instruction Governing Ethicon Change Control
	Procedures
PR800-002	Company Procedure for Test Method Validation
PR800-012	Work Instruction for Design Changes to Existing
	Products
PR602-003	Company Procedure for Design Risk Management
PR161-001	Work Instructions for Equipment and Process Control
	Procedure
OP603-276	Work Instructions for the Design and Development of
	Computer Systems
OP650-010	Operating Procedure for Design Safety Assessment
21 CFR Part 820	Quality System Regulation
ISO 13485	Quality systems – Medical devices – System
	requirements for regulatory purposes

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